CDC UPDATE
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NCHSTP National Center for HIV, STD & TB PREVENTION

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Testing a Vaccine Designed to Help Curb the Devastating Toll of HIV in the Developing World

CDC Supports Thai Health Officials and VaxGen in Collaborative Effort

It is estimated that over 30 million individuals worldwide are infected with HIV–the vast majority of whom live in the developing world.[1] One country in particular, Thailand, has experienced a rapidly escalating and severe HIV epidemic since 1988. Among the 60 million inhabitants of Thailand, as many as 800,000 people are currently believed to be living with HIV.

Despite innovative and persistent prevention efforts, HIV continues to spread rapidly, particularly among Thailand's population of injection drug users (IDUs). Methadone treatment, education and counseling on HIV prevention, and easy access to sterile needles have certainly helped to slow the epidemic. Yet, among IDUs in Bangkok, 6% continue to become infected each year. In addition to being one of the nations most severely affected by HIV, Thailand has emerged as one of the nations most committed to ending its toll.

To address the urgent need for an HIV vaccine, Thai officials have been working with the World Health Organization, the Joint United Nations Program on HIV/AIDS (UNAIDS), the International AIDS Vaccine Initiative (IAVI), the Government of Japan, the U.S. National Institutes of Health (NIH), the U.S. Department of Defense, various universities, and the Centers for Disease Control and Prevention (CDC) since 1991 to prepare for HIV vaccine efficacy trials. In February 1999, Thailand became the first developing nation to announce a Phase III vaccine field trial. A Phase III trial is done to determine if a vaccine is effective in protecting against infection or disease and is an important step in the evaluation process leading to licensure.

AIDSVAX Phase III trial in Thailand

As part of the Thai National Plan for HIV vaccine research, the Bangkok Metropolitan Administration (BMA) is leading the 3-year collaborative research trial to evaluate the ability of AIDSVAX to prevent HIV infection among uninfected IDUs in Bangkok, Thailand. AIDSVAX was developed by VaxGen, a U.S. vaccine developer. BMA is conducting the trial in conjunction with VaxGen, the Mahidol University Faculty of Tropical Medicine in Bangkok, and the HIV/AIDS Collaboration (a longstanding research collaboration between the Thai Ministry of Public Health and CDC).

The trial is being conducted among uninfected IDUs attending 17 drug treatment clinics in Bangkok. The design is a randomized, double-blind, placebo-controlled trial in which half of the 2,500 volunteers receive the AIDSVAX vaccine and the other half receive placebo injections that do not include the vaccine. Neither the researchers nor the participants know which participants are in each half of the trial.

To guard against the relaxation of preventive behaviors, all volunteers receive extensive counseling on how to protect themselves against HIV infection, as well as explicit warnings that this vaccine may not protect them from infection. To further ensure that trial participants are not inadvertently placed at any risk, the trial design, as well as all procedures and protocols for study recruitment and counseling, have received extensive scientific and ethics review by Institutional Review Boards and ethics committees of all involved agencies, both the Thai and U.S. government, and the Joint United Nations Program on HIV/AIDS.

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[1] *UNAIDS Joint United Nations Programme on HIV/AIDS. AIDS epidemic update: December 1998*

About AIDSVAX

AIDSVAX is a "bivalent" vaccine, meaning it is composed of gp120 proteins found on the outer envelope of two strains of HIV. The version of the vaccine being tested in Thailand is designed to induce antibodies to HIV-1 subtypes B and E, the subtypes of HIV most common in South East Asia and the Pacific Rim. VaxGen is currently evaluating another version of AIDSVAX designed to protect against strains common in North America among 5,000 volunteers in multiple sites throughout the United States. Thai health officials played a leading role in acknowledging the critical need for a vaccine designed for use in Thailand to protect against strains of both subtypes B and E. Early reports from several smaller trials of AIDSVAX in Thailand and the United States, involving about 2,000 persons, have shown the vaccine to be safe and capable of inducing antibodies against these strains of HIV.

U.S. Vaccine Research

Although AIDSVAX is the first vaccine to move to Phase lll trials in a developing country, as well as in the United States, it is only one of a series of vaccines that are in various stages of the development process. The National Institutes of Health (NIH) is the agency responsible for coordinating the simultaneous evaluation of multiple vaccine candidates in the United States.

CDC's Role in Vaccine Research and Evaluation
Maintaining Progress in Prevention as We Strive for New Solutions

CDC is the United States' lead federal agency for prevention, including HIV prevention. CDC has nearly two decades of experience in designing and evaluating programs to reduce the spread of HIV among populations at risk. Additionally, the agency has a long history of vaccine development and evaluation with other diseases (measles, hepatitis B, and polio). CDC shares the ultimate goal of all of those working to stop the HIV and AIDS epidemic–a vaccine to prevent infection. As we work toward this goal through this and other vaccine trials, it is critical that we not endanger progress already made in HIV prevention and that neither individuals involved in nor those outside of studies abandon safer sex and drug-related behaviors proven to prevent infection.

CDC's Role in the Thailand Trial

CDC's primary role in the Thailand trial is two-fold. First, continuing a longstanding research collaboration, CDC has worked closely with the Thai government for several years to help them prepare to implement vaccine studies. Since 1995, this collaboration has involved a range of activities, including measuring the level of new infections in Thailand, identifying a group of individuals who are willing to participate in a trial and can be followed over time to evaluate risk behaviors and infection, and working with the community to build the understanding and support necessary to implement the trial. Second, CDC has worked, and will continue to work, with Thai health officials and VaxGen to ensure that individuals in the trial receive appropriate risk-reduction counseling and are fully educated about how the trial works, the potential risks and benefits of participation, and the need for maintaining good behavioral risk-reduction practices during the trial.

For example, as the trial proceeds, CDC will evaluate the impact of the trial on both participant and community attitudes and behaviors. This information will be critical not only to this community, but also to the future evaluation and implementation of vaccine strategies. CDC is not providing direct financial support for this trial but will provide logistical, laboratory, and data analysis support throughout the trial. CDC hopes that this and other vaccine trials underway will identify an HIV vaccine to help end this epidemic. Until such a solution is available, we must continue to reinforce the already proven behavioral and biomedical methods of HIV prevention.